

Exhibit 1

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

SALIX PHARMACEUTICALS, INC., SALIX
PHARMACEUTICALS, LTD., ALFASIGMA
S.P.A. and BAUSCH HEALTH IRELAND
LTD.,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS OF NEW
YORK, LLC, et al.,

Defendants.

Civil Action No. 1:24-4607 (JFM)
(Consolidated)

**DEFENDANTS ZYDUS PHARMACEUTICALS (USA) INC. AND
ZYDUS LIFESCIENCES LIMITED’S OBJECTIONS AND RESPONSES TO
PLAINTIFFS’ FIRST SET OF REQUESTS TO DEFENDANTS FOR THE
PRODUCTION OF DOCUMENTS AND THINGS (NOS. 1-76)**

Defendants Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited, (collectively, “Zydus”), in accordance with Rules 26 and 34 of the Federal Rules of Civil Procedure and the Local Rules of the United States District Court for the District of New Jersey, object and respond to Plaintiffs Salix Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd., Alfasigma S.P.A. and Bausch Health Ireland Ltd. (collectively, “Plaintiffs”) First Set of Requests for the Production of Documents and Things (Nos. 1-76) (“Requests”), dated February 10, 2025, as follows.¹

¹ Plaintiffs’ First Set of Requests to Defendants for the Production of Documents and Things (Nos. 1-76) seek production of “all documents and things in the possession, custody, or control of Zydus Pharmaceuticals, LLC.” There is not entity named “Zydus Pharmaceuticals, LLC” that is a party to this action.

PRELIMINARY STATEMENT

1. Zydus's investigation into the facts and circumstances regarding this matter continues. Zydus's responses to the Requests are without prejudice to, and do not constitute a waiver of, Zydus's right to rely on other documents or information at trial. Zydus also reserves the right to supplement these responses from time to time as may be appropriate.

2. Zydus's responses to the Requests shall not be construed as a representation that Zydus has any responsive documents or information in its possession, custody, or control; that documents exist in addition to those that may already have been produced; that Zydus has performed any of the acts described in the Requests; or that Zydus acquiesces to the characterization of the conduct or activities described in the Requests.

3. Where Zydus has agreed to produce documents, Zydus will do so by conducting a reasonable search of logical repositories for such documents, subject to the terms and conditions of any discovery agreements between the parties, including but not limited to any agreement on the collection and production of ESI. Zydus will produce non-privileged, non-duplicative documents to Plaintiffs, or will make any such documents available for inspection and copying, at a mutually agreed-upon date and time.

4. Nothing in Zydus's responses shall be construed as a waiver of any of Zydus's rights or objections that otherwise might be available to Zydus, nor shall Zydus's responses be deemed an admission of relevancy, materiality, or admissibility into evidence of the Requests or the responses thereto. Further, Zydus reserves the right to redact from its responses any matter that is not called for, has been objected to by Zydus, or is irrelevant to the issues in this litigation.

5. These objections and responses are made solely for the purpose of discovery in the present litigation. Nothing in Zydus's responses is intended to waive the following objections, which are expressly reserved: all objections as to relevance, authenticity, propriety, materiality,

and admissibility of the subject matter of the documents produced; all objections as to vagueness, ambiguity, or undue burden; all objections on any ground as to the use of any documents provided in response to any request; all objections on any ground to any request for further responses to these or other discovery requests; and any and all other objections and grounds that would or could require or permit the exclusion of any information, document, or statement therein from evidence, all of which objections and grounds are reserved and may be interposed at a hearing in this litigation.

6. Any documents or things provided by Zydus in response to these Requests will be produced at a mutually convenient time and place pursuant to the terms of the Discovery Confidentiality Order to be entered by the Court.

7. Any statement that Zydus will produce documents responsive to a Request does not mean that documents subject to production exist or that documents exist in addition to those that have already been produced, but rather means that such documents located after a reasonable search will be produced.

8. In the event that any privileged or immune document is produced by Zydus, such production is inadvertent and is not intended as a waiver of any privilege or immunity. In the event that Plaintiffs believe they may have received any privileged or immune information, they should promptly inform Zydus, return or destroy all documents constituting or referencing such information, and refrain from using such information in any way.

9. Zydus has objected and responded to the Requests as it interprets and understands each of them. If Plaintiffs subsequently assert an interpretation of any of the Requests that differs from Zydus's understanding, Zydus reserves the right to supplement its objections and responses.

GENERAL OBJECTIONS

1. Zydus objects to the Requests to the extent they seek to impose upon Zydus obligations greater than those authorized by the Federal Rules of Civil Procedure, the Local Rules, or any other applicable rule, precedent, or court order.

2. Zydus objects to the Requests to the extent they seek documents or information that exceed the scope of permissible discovery by calling for documents or information that are neither relevant to any party's claims or defenses nor proportional to the needs of the case.

3. Zydus objects to the Requests to the extent they purport to require Zydus to search for or produce documents or information regarding drug products other than XIFAXAN® or the proposed final product described in ANDA No. 218650.

4. Zydus objects to the Requests to the extent that: (i) the discovery sought by any Request is unreasonably cumulative or duplicative or is obtainable from some other source that is more convenient, less burdensome, or less expensive; or (ii) compliance with any Request would be unduly burdensome, expensive, or oppressive.

5. Zydus objects to the Requests to the extent they seek documents or information protected by the attorney-client privilege, the work-product doctrine, or any applicable privilege or immunity recognized by a domestic or foreign tribunal.

6. Zydus objects to the Requests to the extent they seek documents or information that are confidential or proprietary to Zydus.

7. Zydus objects to the Requests to the extent they seek documents or information that have already been produced or are already known or available to Plaintiffs.

8. Zydus objects to the Requests to the extent they purport to require Zydus to search for or produce documents not within Zydus's possession, custody, or control within the meaning of the Federal Rules of Civil Procedure. *See* Fed. R. Civ. P. 34(a).

9. Zydus objects to the Requests to the extent they seek documents or information which, if furnished, would violate any domestic or foreign judicial order, protective order, or stipulation of confidentiality that has been entered with respect to such documents or information.

10. Zydus objects to the Requests as overbroad and unduly burdensome to the extent they purport to require Zydus, without limitation, to search for “all” or “any” documents, things, correspondence, or the like, on a subject as overly broad, unduly burdensome, and not limited in scope as to time.

11. Zydus objects to the Requests as premature to the extent they seek documents or information regarding expert discovery or otherwise seek expert discovery or opinions in advance of this Court’s Scheduling Order (D.I. 29).

12. Zydus objects to the Requests to the extent they seek disclosure of information in violation of the legal or contractual obligations of Zydus to third parties, including but not limited to obligations arising out of non-disclosure or confidentiality agreements. Zydus will provide such information to the extent it can do so consistent with its obligations to any third parties.

13. Zydus objects to the Requests as overbroad, unduly burdensome, and exceeding the scope of permissible discovery to the extent they either fail to specify a time frame or specify a time frame beyond that which is relevant to this litigation. Accordingly, unless otherwise stated in a Response to a specific Request, Zydus will produce responsive, non-duplicative, non-privileged documents and things based on a reasonable and diligent search to the extent documents and things that are dated before September 27, 2024, and that are relevant to this litigation and/or proportional to the needs of this case.

14. Zydus objects to the Requests to the extent they call for legal opinions or conclusions.

OBJECTIONS TO DEFINITIONS

1. Zydus objects to all of Plaintiffs' definitions to the extent that they are overbroad, unduly burdensome, and seek documents or information that are neither relevant to any party's claim or defense in this litigation nor proportional to the needs of the case. Zydus further objects to the definitions to the extent that they seek to impose upon Zydus obligations greater than those authorized by the Federal Rules of Civil Procedure, including but not limited to Rules 26 and 34, and any applicable Local Rules and court orders.

2. Zydus objects to all of the definitions to the extent that they: (1) change the common meaning of the English language with regard to any word or phrase, (2) alter the scope of discovery under the Federal Rules of Civil Procedure, (3) define terms differently than such terms are defined under the Federal Rules of Civil Procedure and/or the common law, and/or (4) exceed the requirements of the Federal Rules of Civil Procedure, Local Rules, other applicable rules, or applicable precedent or court order. Zydus also objects to all of the definitions to the extent that they are overbroad, argumentative, prejudicial, improper, incorrect, vague, and/or ambiguous.

3. Zydus objects to the definition of "Plaintiffs" and "Salix" as vague and ambiguous, at least with respect to "shall mean individually or collectively, as the context requires."

4. Zydus objects to the definition of "Zydus Pharmaceuticals (USA) Inc." as overbroad, unduly burdensome, and seeking documents and information that are neither relevant to the claims or defenses of any party nor proportional to the needs of this case, at least with respect to "all officers, directors, employees, partners, members, owners, agents, representatives, attorneys, and any other person under the control of Zydus Pharmaceuticals (USA) Inc., including all parents, divisions, subsidiaries, affiliates, corporate predecessors, and successors of Zydus Pharmaceuticals (USA) Inc. whether wholly or partially owned." Zydus further objects to this definition as purporting to impose upon Zydus an obligation to collect and produce information

and documents outside of Zydus's possession, custody, or control, at least with respect to third parties. Zydus further objects to this definition to the extent it seeks privileged information.

5. Zydus objects to the definition of "Zydus Lifesciences Limited" as overbroad, unduly burdensome, and seeking documents and information that are neither relevant to the claims or defenses of any party nor proportional to the needs of this case, at least with respect to "all officers, directors, employees, partners, members, owners, agents, representatives, attorneys, and any other person under the control of Zydus Lifesciences Limited, including all parents divisions, subsidiaries, affiliates, corporate predecessors, and successors of Zydus Lifesciences Limited, whether wholly or partially owned." Zydus further objects to this definition as purporting to impose upon Zydus an obligation to collect and produce information and documents outside of Zydus's possession, custody, or control, at least with respect to third parties. Zydus further objects to this definition to the extent it seeks privileged information.

6. Zydus objects to the definition of "Zydus," "you," and "your" as vague and ambiguous, at least with respect to "shall mean individually or collectively, as the context requires."

7. Zydus objects to the definition of "NDA" as overbroad, unduly burdensome, and seeking documents or information that are neither relevant to any party's claims or defenses nor proportional to the needs of the case, at least with respect to "all amendments, supplements, attachments, and additions thereto." Zydus further objects to this definition to the extent it attempts to impose obligations that are inconsistent with or exceed the requirements of Rules 26, 33, and 34 of the Federal Rules of Civil Procedure, any applicable Local Rules, any other applicable rules, precedents, or court orders, or any agreements entered into by the parties.

8. Zydus objects to the definition of “ANDA” as overbroad, unduly burdensome, and seeking documents or information that are neither relevant to any party’s claims or defenses nor proportional to the needs of the case, at least with respect to “all amendments, supplements, attachments, and additions thereto.” Zydus further objects to this definition to the extent it attempts to impose obligations that are inconsistent with or exceed the requirements of Rules 26, 33, and 34 of the Federal Rules of Civil Procedure, any applicable Local Rules, any other applicable rules, precedents, or court orders, or any agreements entered into by the parties.

9. Zydus objects to the definition of “NDA No. 021361” as overbroad, unduly burdensome, and seeking documents or information that are neither relevant to any party’s claims or defenses nor proportional to the needs of the case, at least with respect to “the NDA held by Salix Pharmaceuticals, Inc. for Xifaxan[®] 200 mg tablets.”

10. Zydus objects to the definition of “ANDA No. 218650” and “Zydus’s ANDA” as overbroad, unduly burdensome, and seeking documents or information that are neither relevant to any party’s claims or defenses nor proportional to the needs of the case, at least with respect to “all amendments, supplements, attachments, and additions thereto, without restriction as to date.” Zydus further objects to this definition to the extent it attempts to impose obligations that are inconsistent with or exceed the requirements of Rules 26, 33, and 34 of the Federal Rules of Civil Procedure, any applicable Local Rules, any other applicable rules, precedents, or court orders, or any agreements entered into by the parties.

11. Zydus objects to the definition of “patent certification” as overbroad, unduly burdensome, and seeking documents or information that are neither relevant to any party’s claims or defenses nor proportional to the needs of the case, at least with respect to “any certification,

pursuant to 21 U.S.C. § 355(j).” Zydus objects to this definition as vague and ambiguous, at least with respect to “any certification, pursuant to 21 U.S.C. § 355(j).”

12. Zydus objects to the definition of “Notice Letter” as overbroad, unduly burdensome, and seeking documents or information that are neither relevant to any party’s claims or defenses nor proportional to the needs of the case, at least with respect to “the letter(s) from you notifying Plaintiffs of a patent certification concerning ANDA No. 218650.” Zydus objects to this definition as vague and ambiguous, at least with respect to “the letter(s) from you notifying Plaintiffs of a patent certification concerning ANDA No. 218650.”

13. Zydus objects to the definition of “Prior Art” as overbroad, unduly burdensome, and seeking documents or information that are neither relevant to any party’s claims or defenses nor proportional to the needs of the case, at least with respect to “any publication, disclosure, event, invention, sale, advertisement, or other thing falling within the bounds of pre-AIA and post-AIA 35 U.S.C. §§ 102 and/or 103.” Zydus objects to this definition as vague and ambiguous, at least with respect to “or other thing falling within the bounds of pre-AIA and post-AIA 35 U.S.C. §§ 102 and/or 103.”

14. Zydus objects to the definition of “document” as overbroad, unduly burdensome, and seeking documents or information that are neither relevant to any party’s claims or defenses nor proportional to the needs of the case, at least with respect to “including, but not limited to, electronically stored information and all tangible embodiments, manifestations, or evidence of a communication.” Zydus further objects to this definition as vague and ambiguous, at least with respect to “the comprehensive meaning set forth in Rule 34 of the Federal Rules of Civil Procedure” and “all tangible embodiments, manifestations, or evidence of a communication.” Zydus further objects to this definition to the extent it attempts to impose obligations that are

inconsistent with or exceed the requirements of Rules 26, 33, and 34 of the Federal Rules of Civil Procedure, any applicable Local Rules, any other applicable rules, precedents, or court orders, or any agreements entered into by the parties.

15. Zydus objects to the definition of “communication” as overbroad, unduly burdensome, and seeking documents or information that are neither relevant to any party’s claims or defenses nor proportional to the needs of the case, at least with respect to “any and all forms of information transmission or storage,, including, but not limited to, written, oral, electronic, telephonic, or videographic inquiries, discussions, conversations, negotiations, agreements, understandings, meetings, letters, notes, telegrams, advertisements, comments, and interviews, and all documents (as defined above) related to such communications.” Zydus further objects to this definition as vague and ambiguous, at least with respect to “information transmission or storage” and “all documents (as defined above) related.” Zydus further objects to this definition to the extent it attempts to impose obligations that are inconsistent with or exceed the requirements of Rules 26, 33, and 34 of the Federal Rules of Civil Procedure, any applicable Local Rules, any other applicable rules, precedents, or court orders, or any agreements entered into by the parties.

16. Zydus objects to the definition of “thing” as overbroad, unduly burdensome, and seeking documents and information that are neither relevant to the claims or defenses of any party, nor proportional to the needs of this case, at least with respect to “any kind of sample, model, article, device, apparatus, physical specimen, or other tangible item.” Zydus further objects to this definition as vague and ambiguous, at least with respect to “the comprehensive meaning set forth in Rule 34 of the Federal Rules of Civil Procedure” and “any other tangible item.” Zydus objects to the definition to the extent it imposes obligations inconsistent with and/or exceeds the

requirements of Federal Rules of Civil Procedure 26 and 34, any applicable Local Rules, any court orders, or any agreements entered into by the parties.

17. Zydus objects to the definition of “‘identify’ in the case of individuals, organizations, or firms” as overbroad, unduly burdensome, and seeking documents and information that are neither relevant to the claims or defenses of any party, nor proportional to the needs of this case, at least with respect to “the names, current business, addresses, and phone numbers” and “the current residential address, or if unknown, the last known residential address, and business positions and titles.”

18. Zydus objects to the definition of “‘identify’ in the case of documents and things” as overbroad, unduly burdensome, and seeking documents and information that are neither relevant to the claims or defenses of any party, nor proportional to the needs of this case, at least with respect to “including a brief description of such document or thing sufficient to support a request for production and consisting of at least a description of: a. The type of document or thing; b. Its date; c. It’s general subject matter; d. The author, designated addresses, designated recipients, and all person who received or saw copies of the document or thing; e. The custodian of the document or thing identified by name, job title, employer and address; f. The place where the document or thing may be inspected; and g. If a copy of the document or thing has been previously produced to Plaintiffs, a specific and individual identification of the previously supplied document or thing by production number(s).” Zydus further objects to this definition as vague and ambiguous, at least with respect to “a brief description,” “[t]he type of document or thing,” and “[i]ts general subject matter.” Zydus objects to the definition to the extent it imposes obligations inconsistent with and/or exceeds the requirements of Federal Rules of Civil Procedure 26 and 34, any applicable Local Rules, any court orders, or any agreements entered into by the parties.

19. Zydus objects to the definition of “Person” as overly broad and unduly burdensome, and seeking information that is neither relevant to the claims or defenses of any party nor proportional to the needs of this case, at least with respect to “any business, legal, or government entity or organization, including divisions, subsidiaries, departments, and other units therein, and includes any officers, agents or employees thereof.” Zydus further objects to this definition as purporting to impose upon Zydus an obligation to collect and produce information and documents outside of Zydus’s possession, custody, or control, at least with respect to third parties.

20. Zydus objects to the definition of “concerning,” “relating,” and “relate” as overbroad, unduly burdensome, and seeking documents or information that are neither relevant to any party’s claims or defenses nor proportional to the needs of the case, at least with respect to “comprising, pertaining, describing, referring, evidencing, discussing, showing, supporting, contradicting, refuting, constituting, embodying, containing, reflecting, identifying, summarizing, or reporting, or in any way logically or factually connected with the matter discussed.” Zydus further objects to this definition as vague and ambiguous, at least with respect to “in any way logistically or factually connected with the matter discussed.” Zydus further objects to this definition as purporting to impose upon Zydus an obligation to collect and produce information and documents outside of Zydus’s possession, custody, or control, at least with respect to third parties.

21. Zydus objects to the definitions “and” and “or” to the extent they impose obligations inconsistent with and/or exceed the requirements of Federal Rules of Civil Procedure 26 and 34, any applicable Local Rules, any court orders, or any agreements entered into by the parties.

22. Zydus objects to the definition of “possession,” “custody,” and “control” as overbroad, unduly burdensome, and seeking documents or information that are neither relevant to

any party's claims or defenses nor proportional to the needs of the case, at least with respect to "a comprehensive sense to refer to possession, custody, or control by any one or a combination of the following persons or organizations: a. Zydus; b. Any corporation or entity controlled by or affiliated with Zydus or controlling Zydus as their wholly-owned subsidiary; c. Any principal, officer, employee, agent, representative, or a consultant of or for Zydus or any such controlled or affiliated corporation or entity; and d. Counsel for Zydus and any such controlled or affiliated corporation or entity." Zydus further objects to these definitions to the extent they impose obligations inconsistent with and/or exceed the requirements of Federal Rules of Civil Procedure 26 and 34, any applicable Local Rules, any court orders, or any agreements entered into by the parties. Zydus further objects to these definitions as purporting to impose upon Zydus an obligation to collect and produce information and documents outside of Zydus's possession, custody, or control, at least with respect to third parties.

OBJECTIONS TO INSTRUCTIONS

1. Zydus objects to all Instructions to the extent that they are overbroad, unduly burdensome, or seek documents or information that are neither relevant to any party's claim or defense in this litigation nor proportional to the needs of the case. Zydus further objects to the Instructions to the extent they seek to impose upon Zydus obligations greater than those authorized by the Federal Rules of Civil Procedure, the Local Rules, or any other applicable rule, precedent, or court order.

2. Zydus objects to Instruction No. 1 as overbroad, unduly burdensome, and to the extent that it seeks to impose upon Zydus obligations that exceed Federal Rules of Civil Procedure 26 and 37. Zydus will supplement, if necessary, in conformance with the Federal Rules.

3. Zydus objects to Instruction No. 2 as overbroad, unduly burdensome, and to the extent it seeks to impose upon Zydus obligations that exceed the Federal Rules of Civil Procedure 26 and 34. Zydus will set forth its responses and objections in conformance with the Federal Rules.

4. Zydus objects to Instruction No. 3 as overbroad, unduly burdensome, and to the extent that it seeks to impose upon Zydus obligations that exceed the Federal Rules of Civil Procedure 26 and 34. Zydus will set forth its responses and objections in conformance with the Federal Rules.

5. Zydus objects to Instruction No. 4 as overbroad, unduly burdensome, and to the extent that it seeks to impose upon Zydus obligations that exceed Federal Rules of Civil Procedure 26(e). Zydus will supplement, if necessary, in conformance with the Federal Rules and Local Rules.

6. Zydus objects to Instruction No. 5 as overly broad, unduly burdensome, and to the extent that it seeks to impose upon Zydus obligations that exceed the Federal Rules of Civil Procedure 26 and 34. Zydus further objects to this Instruction as vague and ambiguous, at least with respect to “[a]ll documents, communications, or things that are responsive in whole or in part.” Zydus will set forth its responses and objections in conformance with the Federal Rules.

7. Zydus objects to Instruction No. 6 as overbroad, unduly burdensome, and to the extent that it seeks to impose upon Zydus obligations that exceed at least Federal Rule of Civil Procedure 26 and 34. Zydus will set forth its responses and objections in conformance with the Federal Rules.

8. Zydus objects to Instruction No. 7 as overly broad, unduly burdensome, and to the extent that it seeks to impose upon Zydus obligations that exceed at least Federal Rule of Civil

Procedure 26(b)(5) and 34(b)(2). If Zydus withholds documents and information based on a claim of attorney-client privilege, work product immunity, or any other privilege or immunity, Zydus will make the claim in conformance with the Federal Rules.

9. Zydus objects to Instruction No. 8 to the extent that it seeks to impose upon Zydus obligations that exceed at least Federal Rule of Civil Procedure 26 and 34. Zydus will set forth its responses and objections in conformance with the Federal Rules.

OBJECTIONS AND RESPONSES TO REQUESTS FOR PRODUCTION

Zydus incorporates its Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions into its response to each Request. Zydus's responses are subject to, and not a waiver of, Zydus's Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions.

REQUEST FOR PRODUCTION NO. 1:

A complete copy of ANDA No. 218650, each draft of any portion thereof, and each amendment, revision, supplement, attachment, or any accompanying material thereto.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents that are neither relevant to any party's claims or defenses nor proportional to the needs of this case, at least with respect to "[a] complete copy," "each draft of any portion thereof" "each amendment, revision, supplement, attachment," and "any accompanying material thereto. Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity the documents requested, at least with respect to "any accompanying material thereto." Zydus further objects to this Request to the extent it seeks documents already in Plaintiffs' possession, custody, or control or that have already been produced to Plaintiffs. Zydus further objects to this Request to the extent that it seeks documents or

information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity.

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus has produced ANDA No. 218650 and will produce amendments or supplements to ANDA No. 218650, if any, to the extent they have not already been produced. Zydus does not currently intend to produce any other documents in response to this Request.

REQUEST FOR PRODUCTION NO. 2:

All documents, communications, and things concerning your filing of ANDA No. 218650.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents that are neither relevant to any party's claims or defenses nor proportional to the needs of this case, at least with respect to "[a]ll documents, communications, and things." Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to "[a]ll documents, communications, and things concerning your filing." Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents already in Plaintiffs' possession, custody, or control or that have already been produced to Plaintiffs.

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus has produced ANDA No. 218650 and will produce amendments or supplements to ANDA No. 218650, if any, to the extent they have not already been

produced. Zydus does not currently intend to produce any other documents in response to this Request.

REQUEST FOR PRODUCTION NO. 3:

Documents, communications, and things sufficient to identify each company, person, business entity, and law firm that advised or assisted in the preparation or filing of your ANDA No. 218650.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents that are neither relevant to any party's claims or defenses nor proportional to the needs of this case, at least with respect to "[d]ocuments, communications, and things sufficient to identify each company, person, business entity, and law firm that advised or assisted in the preparation or filing of your ANDA No. 218650." Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to "[d]ocuments, communications, and things sufficient to identify" and "advised or assisted." Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other applicable privileges or immunities. Zydus further objects to this Request to the extent it seeks documents already in Plaintiffs' possession, custody, or control or that have already been produced to Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this request.

REQUEST FOR PRODUCTION NO. 4:

All documents concerning all submissions, filings, correspondence, communications and contacts between you and FDA regarding Zydus's ANDA.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents that are neither relevant to any party's claims or defenses nor proportional to the needs of this case, at least with respect to "[a]ll documents, concerning all submissions, filings, correspondence, communications and contacts between you and FDA regarding Zydus's ANDA." Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to "[a]ll documents, concerning all submissions, filings, correspondence, communications and contacts." Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other applicable privileges or immunities. Zydus further objects to this Request to the extent it seeks documents already in Plaintiffs' possession, custody, or control or that have already been produced to Plaintiffs.

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus has produced ANDA No. 218650 and correspondence with the FDA pertaining to ANDA No. 218650 and will produce amendments or supplements to ANDA No. 218650, if any, and additional correspondence with the FDA pertaining to ANDA No. 218650, if any, to the extent they have not already been produced. Zydus does not currently intend to produce any other documents in response to this Request.

REQUEST FOR PRODUCTION NO. 5:

One hundred (100) unexpired samples of Zydus's ANDA Product to be produced from the four most recent manufacturing scale lots (e.g., twenty-five (25) samples from each lot), in the packaging configuration(s) that you intend to market if ANDA No. 218650 is approved by FDA with the addition of a temperature monitor to monitor the temperature of the samples during shipping; and documents evidencing the date of manufacture, date of expiration, and previous storage conditions for all of the foregoing samples.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and to the extent it seeks documents or information that are neither relevant to any party's claims or defenses nor proportional to the needs of the case, at least with respect to "[o]ne hundred (100) unexpired samples of Zydus's ANDA Product to be produced from the four most recent manufacturing scale lots (e.g., twenty-five (25) samples from each lot), in the packaging configuration(s) that you intend to market if ANDA No. 218650 is approved by FDA" and "with the addition of a temperature monitor to monitor the temperature of the samples during shipping; and documents evidencing the date of manufacture, date of expiration, and previous storage conditions for all of the foregoing samples." Zydus further objects to this Request as vague, ambiguous, and failing to identify the requested documents with reasonable particularity, at least with respect to "documents evidencing the date of manufacture, date of expiration, and previous storage conditions for all of the foregoing samples."

Subject to and without waiting any of its general or specific objections, and to the extent Zydus understands this Request, Zydus will produce one bottle of 60 tablets from each of batches KE30060, KE30124, and KE30125 of the proposed final product described in ANDA No. 218650 ("Zydus's Proposed ANDA Product") for a total of 180 samples following receipt by Zydus of mutually acceptable delivery instructions from Plaintiffs. Zydus does not currently intend to produce any other documents or things in response to this request.

REQUEST FOR PRODUCTION NO. 6:

A five (5) gram sample of the rifaximin active ingredient used in the manufacture of the four most recent manufacturing scale lots of Zydus's ANDA Product (e.g., five (5) grams from each lot if multiple lots were used), shipped with a temperature monitor to monitor the temperature of the samples during shipping; and documents evidencing the date of manufacture, date of expiration, and previous storage conditions for the foregoing sample.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and to the extent it seeks documents or information that are neither relevant to any party's claims or defenses nor proportional to the needs of the case, at least with respect to "five (5) gram sample of the rifaximin active ingredient used in the manufacture of the four most recent manufacturing scale lots of Zydus's ANDA Product (e.g., five (5) grams from each lot if multiple lots were used), shipped with a temperature monitor to monitor the temperature of the samples during shipping; and documents evidencing the date of manufacture, date of expiration, and previous storage conditions for the foregoing sample." Zydus further objects to this Request as vague, ambiguous, and failing to identify the requested documents with reasonable particularity, at least with respect to "documents evidencing the date of manufacture, date of expiration, and previous storage conditions for the foregoing sample."

Subject to and without waiting any of its general or specific objections, and to the extent Zydus understands this Request, Zydus is willing to meet and confer with Plaintiffs about the production of a reasonable and proportional amount of unexpired drug substance, if any, used in Zydus's Proposed ANDA Product. Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 7:

An unexpired five (5) gram sample of each of the excipients used in the manufacture of your four most recent manufacturing scale lots of Zydus's ANDA Product (e.g., five (5) grams from each lot if multiple lots were used) shipped with a temperature monitor to monitor the temperature of the samples during shipping; and documents evidencing the date of manufacture, date of expiration, and previous storage conditions for the foregoing samples.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and to the extent it seeks documents or information that are neither relevant to any party's claims or defenses nor

proportional to the needs of the case, at least with respect to “unexpired five (5) gram sample of each of the excipients used in the manufacture of your four most recent manufacturing scale lots of Zydus’s ANDA Product (e.g., five (5) grams from each lot if multiple lots were used) shipped with a temperature monitor to monitor the temperature of the samples during shipping; and documents evidencing the date of manufacture, date of expiration, and previous storage conditions for the foregoing samples.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the requested documents with reasonable particularity, at least with respect to “documents evidencing the date of manufacture, date of expiration, and previous storage conditions for the foregoing samples.” Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 8:

Twenty-five (25) samples of placebo tablets and five (5) grams of placebo blend that reflects the ingredients and composition of Zydus’s ANDA Product, shipped with a temperature monitor to monitor the temperature of the samples during shipping; and documents evidencing the date of manufacture, date of expiration, and previous storage conditions for the foregoing samples.

RESPONSE:

Zydus objects to this Request as seeking things that are neither relevant to the claims or defenses of any party nor proportional to the needs of this case, at least with respect to “[t]wenty-five (25) samples of placebo tablets and five (5) grams of placebo blend that reflects the ingredients and composition of Zydus’s ANDA Product,” “shipped with a temperature monitor to monitor the temperature of the samples during shipping,” and “documents evidencing the date of manufacture, date of expiration, and previous storage conditions for the foregoing samples.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity the documents requested, at least with respect to “documents evidencing the date of manufacture, date of expiration, and previous storage conditions for the foregoing

samples.” Zydus further objects to this Request to the extent it is as unreasonably duplicative of at least Request No. 7.

Subject to and without waiting any of its general or specific objections, and to the extent Zydus understands this Request, Zydus is willing to meet and confer with Plaintiffs about the production of a reasonable and proportional amount of placebo blend, if any, related to ANDA No. 218650. Zydus does not have any placebo tablets related to ANDA No. 218650 in its possession, custody, or control. Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 9:

Documents, communications, and things related to the storage and transportation conditions for each sample in requests 5-8 that will be produced or were produced to Plaintiffs, including, but not limited to, shipping records and inventory lists.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and to the extent it seeks documents or information that are neither relevant to any party’s claims or defenses nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things related to the storage and transportation conditions for each sample in requests 5-8 that will be produced or were produced to Plaintiffs, including, but not limited to, shipping records and inventory lists.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity the documents requested, at least with respect to “[d]ocuments, communications, and things related to the storage and transportation conditions,” and “shipping records and inventory lists.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other applicable privileges or immunities. Zydus further objects to this Request to the extent it seeks documents already in Plaintiffs’ possession,

custody, or control or that have already been produced to Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 10:

Documents, communications, and things sufficient to identify each batch of Zydus's ANDA Product manufactured within, or that Zydus intends to be sold within, the United States, including for each batch, the date of manufacture, the quantity of Zydus's ANDA Product, the anticipated expiration date, and the present location.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents that are neither relevant to the claims or defenses of any party nor proportional to the needs of this case, at least with respect to “[d]ocuments, communications, and things sufficient to identify each batch of Zydus’s ANDA Product manufactured within, or that Zydus intends to be sold within, the United States” and “including for each batch, the date of manufacture, the quantity of Zydus’s ANDA Product, the anticipated expiration date, and the present location.” Zydus further objects to this Request as vague, ambiguous, overly broad, and unduly burdensome at least with respect to “[d]ocuments, communications, and things sufficient to identify each batch of Zydus’s ANDA Product manufactured within, or that Zydus intends to be sold within, the United States, including for each batch, the date of manufacture, the quantity of Zydus’s ANDA Product, the anticipated expiration date, and the present location.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other applicable privileges or immunities. Zydus further objects to this Request to the extent it seeks documents already in Plaintiffs’ possession, custody, or control or that have already been produced to Plaintiffs.

Subject to and without waiting any of its general or specific objections, and to the extent Zydus understands this Request, Zydus states that Zydus has not manufactured any batches of

Zydus's Proposed ANDA Product within the United States and has not manufactured any batches of Zydus's Proposed ANDA Product that Zydus intends to be sold within the United States. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 11:

Documents, communications, and things concerning your decision to seek FDA approval for Zydus's ANDA Product.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents that are neither relevant to any party's claims or defenses nor proportional to the needs of this case, at least with respect to "[d]ocuments, communications, and things concerning your decision to seek FDA approval for Zydus's ANDA Product." Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to "[d]ocuments, communications, and things concerning your decision to seek FDA approval." Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other applicable privileges or immunities. Zydus further objects to this Request to the extent it seeks documents already in Plaintiffs' possession, custody, or control or that have already been produced to Plaintiffs.

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus will produce non-privileged documents, if any, that are reasonably related to Zydus's business decision to file ANDA No. 218650 located after a reasonable search. Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 12:

Documents, communications, and things concerning the properties, efficacy, benefits, or utility of Zydus's ANDA Product.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents that are neither relevant to any party's claims or defenses nor proportional to the needs of this case, at least with respect to "[d]ocuments, communications, and things concerning the properties, efficacy, benefits, or utility of Zydus's ANDA Product." Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to "[d]ocuments, communications, and things concerning the properties, efficacy, benefits, or utility." Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other applicable privileges or immunities. Zydus further objects to this Request to the extent it seeks documents already in Plaintiffs' possession, custody, or control or that have already been produced to Plaintiffs.

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus is willing to meet and confer with Plaintiffs regarding a more narrowly tailored request. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 13:

A complete copy of any Drug Master File ("DMF") referenced or relied upon in your ANDA No. 218650.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and to the extent it seeks documents that are neither relevant to the claims or defenses of any party nor proportional to the

needs of this case, at least with respect to “[a] complete copy of any Drug Master File (‘DMF’) referenced or relied upon in your ANDA No. 218650.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the requested documents with reasonable particularity, at least with respect to “any DMF.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other applicable privileges or immunities. Zydus further objects to this Request to the extent that it seeks disclosure of information in violation of the legal or contractual obligations of Zydus to third parties, including but not limited to obligations arising out of non-disclosure and/or confidentiality agreements. Zydus further objects to this Request to the extent it purports to require Zydus to search for and/or produce documents not within Zydus’s possession, custody or control. Zydus further objects to this Request to the extent it seeks documents already in Plaintiffs’ possession, custody, or control or that have already been produced to Plaintiffs.

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus will produce the portions of DMF No. 034387 that are in Zydus’s custody, possession, or control. Zydus does not currently intend to produce any other documents in response to this Request.

REQUEST FOR PRODUCTION NO. 14:

Documents, communications, and things sufficient to identify each manufacturer, vendor, or supplier of rifaximin from whom you propose or plan to source such material if ANDA No. 218650 is approved, and documents, communications, and things sufficient to identify any U.S. agent of any such manufacturer, vendor, or supplier.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the

needs of this case, at least with respect to “[d]ocuments, communications, and things sufficient to identify each manufacturer, vendor, or supplier of rifaximin from whom you propose or plan to source such material if ANDA No. 218650 is approved” and “documents, communications, and thing sufficient to identify any U.S. agent of any such manufacturer, vendor, or supplier.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments sufficient to identify any U.S. agent of any such manufacturer, vendor, or supplier.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other applicable privileges or immunities. Zydus further objects to this Request to the extent it purports to require Zydus to search for and/or produce documents not within Zydus’s possession, custody or control. Zydus further objects to this Request to the extent that it seeks disclosure of information in violation of the legal or contractual obligations of Zydus to third parties, including but not limited to obligations arising out of non-disclosure and/or confidentiality agreements. Zydus further objects to this Request to the extent it seeks documents already in Plaintiffs’ possession, custody, or control or that have already been produced to Plaintiffs.

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus has produced ANDA No. 218650 and will produce amendments or supplements to ANDA No. 218650, if any, to the extent they have not already been produced, which identify the manufacturer of the rifaximin drug substance used in the manufacture of Zydus’s Proposed ANDA Product. Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 15:

Documents, communications, and things sufficient to identify each manufacturer, vendor, or supplier of each excipient of Zydus's ANDA Product from whom you propose or plan to source such material if ANDA No. 218650 is approved, and documents, communications, and things sufficient to identify any U.S. agent of any such manufacturer, vendor, or supplier.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of this case, at least with respect to “[d]ocuments, communications, and things sufficient to identify each manufacturer, vendor, or supplier of each excipient of Zydus's ANDA Product from whom you propose or plan to source such material if ANDA No. 218650 is approved” and “documents, communications, and things sufficient to identify any U.S. agent of any such manufacturer, vendor, or supplier.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “documents sufficient to identify any U.S. agent of any such manufacturer, vendor, or supplier.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other applicable privileges or immunities. Zydus further objects to this Request to the extent it purports to require Zydus to search for and/or produce documents not within Zydus's possession, custody or control. Zydus further objects to this Request to the extent that it seeks documents or information that is already in Plaintiffs' possession, custody, or control, and/or has already been produced to Plaintiffs. Zydus further objects to this Request to the extent it seeks documents and things subject to confidentiality agreements, protective orders, or any other obligation to which Zydus is required to protect or maintain the confidentiality of any third party's information or documents.

Subject to and without waiving any of its general or specific objections, , Zydus has produced ANDA No. 218650 and will produce amendments or supplements to ANDA No. 218650, if any, to the extent they have not already been produced, that identify the manufacturer of each excipient used in the manufacture of Zydus's Proposed ANDA Product. Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 16:

Documents, communications, and things concerning any licensing, supply, or other contractual agreement or understanding between you and any other person concerning Zydus's ANDA Product.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things concerning any licensing, supply, or other contractual agreement or understanding between you and any other person concerning Zydus's ANDA Product.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications, and things concerning any licensing, supply, or other contractual agreement or understanding.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other applicable privileges or immunities. Zydus further objects to this Request to the extent it seeks documents and things subject to confidentiality agreements, protective orders, or any other obligation to which Zydus is required to protect or maintain the confidentiality of any third party's information or documents. Zydus further objects to this Request to the extent it purports to require Zydus to search for and/or produce documents not within Zydus's possession, custody or control. Zydus further objects to this Request to the

extent that it seeks documents or information that is already in Plaintiffs' possession, custody, or control, and/or has already been produced to Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 17:

Documents, communications, and things concerning the actual or proposed container and labeling of Zydus's ANDA Product.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to "[d]ocuments, communications, and things concerning the actual or proposed container and labeling of Zydus's ANDA Product." Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to "[d]ocuments, communications, and things concerning the actual or proposed container and labeling." Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other applicable privileges or immunities.

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus has produced ANDA No. 218650 and will produce amendments or supplements to ANDA No. 218650, if any, to the extent they have not already been produced that identify the proposed container and labeling of Zydus's Proposed ANDA Product. Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 18:

Documents, communications, and things concerning the prescription and administration of Zydus's ANDA Product.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of this case, at least with respect to “[d]ocuments, communications, and things concerning the prescription and administration of Zydus's ANDA Product.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications, and things concerning the prescription and administration.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other applicable privileges or immunities. Zydus further objects to this Request to the extent it seeks documents and things subject to confidentiality agreements, protective orders, or any other obligation to which Zydus is required to protect or maintain the confidentiality of any third party's information or documents. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs.

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus's Proposed ANDA Product has not been approved and therefore there is no prescription or administration of Zydus's Proposed ANDA Product. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 19:

Documents, communications, and things concerning your plan for promoting or encouraging the sale or use of Zydus's ANDA Product.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things concerning your plan for promoting or encouraging the sale or use of Zydus’s ANDA Product.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications, and things concerning your plan for promoting or encouraging the sale or use.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other applicable privileges or immunities. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs.

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus’s Proposed ANDA Product has not been approved and therefore there are no plans for promoting or encouraging the sale or use of Zydus’s Proposed ANDA Product. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 20:

Documents, communications, and things concerning your marketing, or planned or proposed marketing, of Zydus’s ANDA Product.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the

needs of the case, at least with respect to “[d]ocuments, communications, and things concerning your marketing, or planned or proposed marketing, of Zydus’s ANDA Product.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications, and things concerning your marketing, or planned or proposed marketing.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other applicable privileges or immunities. Zydus further objects to this Request to the extent that it seeks documents or information that is already in Plaintiffs’ possession, custody, or control, and/or has already been produced to Plaintiffs.

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus’s Proposed ANDA Product has not been approved and therefore there is no marketing, or planned or proposed marketing, of Zydus’s Proposed ANDA Product. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 21:

Documents, communications, and things concerning the market or potential market for Zydus’s ANDA Product.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things concerning the market or potential market for Zydus’s ANDA Product.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity,

at least with respect to “[d]ocuments, communications, and things concerning the market or potential market.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other applicable privileges or immunities. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs.

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus will produce non-privileged, representative sales forecasts prepared by Zydus, if any, for Zydus’s Proposed ANDA Product. Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 22:

Documents, communications, and things concerning your actual or planned advertising of Zydus’s ANDA Product.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things concerning your actual or planned advertising of Zydus’s ANDA Product.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications, and things concerning your actual or planned advertising.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other applicable privileges or immunities. Zydus further objects to

this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs.

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus's Proposed ANDA Product has not been approved and there is no actual or planned advertising of Zydus's Proposed ANDA Product. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 23:

Documents, communications, and things concerning any estimate by or for you regarding sales or demand for Zydus's ANDA Product.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to "[d]ocuments, communications, and things concerning any estimate by or for you regarding sales or demand for Zydus's ANDA Product." Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to "[d]ocuments, communications, and things concerning any estimate by or for you regarding sales or demand." Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs.

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus will produce non-privileged, representative sales forecasts

prepared by Zydus, if any, for Zydus's Proposed ANDA Product. Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 24:

Documents, communications, and things concerning the present and future pricing of Zydus's ANDA Product.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things concerning the present and future pricing of Zydus's ANDA Product.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments communications, and things concerning the present and future pricing.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 25:

Documents, communications, and things concerning your marketing or potential marketing of any product to compete with Xifaxan[®].

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things concerning

your marketing or potential marketing of any product to compete with Xifaxan®.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments and things concerning your marketing or potential marketing of any product.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs.

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus’s Proposed ANDA Product has not been approved and there is no marketing or potential marketing, of Zydus’s Proposed ANDA Product. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 26:

Documents, communications, and things concerning the ways in which you intend to notify and encourage doctors, healthcare organizations, pharmacists, and/or patients about Zydus’s ANDA Product, including, but not limited to, all documents, communications, and things concerning your plans or efforts to encourage doctors, healthcare organizations, pharmacists, and/or patients to switch from Xifaxan® to Zydus’s ANDA Product.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things concerning the ways in which you intend to notify and encourage doctors, healthcare organizations, pharmacists, and/or patients about Zydus’s ANDA Product” and “including, but not limited to, all documents, communications, and things concerning your plans or efforts to encourage doctors, healthcare organizations, pharmacists, and/or patients to switch from Xifaxan® to Zydus’s ANDA

Product.” Zydus further objects to this Request as vague, ambiguous, and failing to describe the documents identified with reasonable particularity, at least with respect to “[d]ocuments, communications, and things concerning the ways in which you intend to notify and encourage” and “all documents, communications, and things concerning your plans or efforts to encourage.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents and things subject to confidentiality agreements, protective orders, or any other obligation to which Zydus is required to protect or maintain the confidentiality of any third party’s information or documents. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs.

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus’s Proposed ANDA Product has not been approved and Zydus does not have any plans to notify and encourage doctors, healthcare organizations, pharmacists, and/or patients about Zydus’s ANDA Product or to encourage doctors, healthcare organizations, pharmacists, and/or patients to switch from Xifaxan[®] to Zydus’s Proposed ANDA Product. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 27:

Documents, communications, and things concerning all work, research, development, design, tests, experiments, evaluations, analyses, or studies, whether complete, incomplete, or prematurely terminated, in the possession of or conducted by or for you concerning Zydus’s ANDA Product.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications and things concerning all work, research, development, design, tests, experiments, evaluations, analyses, or studies,” “whether complete, incomplete, or prematurely terminated,” and “in the possession of or conducted by or for you concerning Zydus’s ANDA Product.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications and things concerning all work, research, development, design, tests, experiments, evaluations, analyses, or studies.” Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity.

Subject to and without waiving any of its general and specific objections, and to the extent Zydus understands this Request, Zydus will produce non-privileged documents within Zydus’s possession, custody, or control, if any, that are reasonably related to the research and development of Zydus’s Proposed ANDA Product. Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 28:

Documents, communications, and things concerning any testing, whether complete, incomplete, or prematurely terminated, including but not limited to, protocols, test results, reports, and x-ray powder diffraction peak results, performed by you or on your behalf concerning polymorphs of rifaximin in Zydus’s ANDA Product.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things concerning any testing, whether complete, incomplete, or prematurely terminated, including but not limited to, protocols, test results, reports, and x-ray powder diffraction peak results, performed by you or on your behalf concerning polymorphs of rifaximin in Zydus’s ANDA Product.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications, and things concerning any testing,” and “protocols, test results, reports, and x-ray powder diffraction peak results.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs.

Subject to and without waiving any of its general and specific objections, and to the extent Zydus understands this Request, Zydus will produce non-privileged documents within Zydus’s possession, custody, or control, if any, that are reasonably related to the testing and analysis of the polymorphic form of Zydus’s Proposed ANDA Product. Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 29:

Documents, communications, and things concerning any testing, whether complete, incomplete, or prematurely terminated, including but not limited to, protocols, test results, reports, and x-ray powder diffraction peak results, performed by you or on your behalf concerning polymorphs of rifaximin in Xifaxan®.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things concerning any testing, whether complete, incomplete, or prematurely terminated” and “including but not limited to, protocols, test results, reports, and x-ray powder diffraction peak results, performed by you or on your behalf concerning polymorphs of rifaximin in Xifaxan®.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications, and things concerning any testing” and “protocols, test results, reports, and x-ray powder diffraction peak results.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs.

Subject to and without waiving any of its general and specific objections, and to the extent Zydus understands this Request, Zydus will produce non-privileged documents within Zydus’s possession, custody, or control, if any, that are reasonably related to the polymorphs of rifaximin in Xifaxan®. Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 30:

Documents, communications, and things generated by persons engaged in any work, research, development, tests, experiments, evaluations, analyses, or studies, whether complete, incomplete, or prematurely terminated on Zydus’s ANDA Product by or for you, including, but not limited to, publications, research notebooks, research summaries, and reports.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things generated by persons engaged in any work, research, development, tests, experiments, evaluations, analyses, or studies, whether complete, incomplete, or prematurely terminated on Zydus’s ANDA Product by or for you” and “including, but not limited to, publications, research notebooks, research summaries, and reports.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications, and things generated by persons engaged in any work, research, development, tests, experiments, evaluations, analyses, or studies.” Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity.

Subject to and without waiving any of its general and specific objections, and to the extent Zydus understands this Request, Zydus will produce non-privileged documents within Zydus’s possession, custody, or control, if any, that are reasonably related to the research and development of Zydus’s Proposed ANDA Product. Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 31:

Documents, communications, and things identifying and concerning all consultants, experts, physicians, and clinicians you consulted regarding any research, development, design, and testing of Zydus’s ANDA Product.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents that are neither relevant to any party's claims or defenses nor proportional to the needs of this case, at least with respect to "[d]ocuments communications, and things identifying and concerning all consultants, experts, physicians, and clinicians you consulted" and "regarding any research, development, design, and testing of Zydus's ANDA Product." Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to "[d]ocuments communications, and things identifying and concerning" and "any research, development, design, and testing of Zydus's ANDA Product." Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, the joint-defense or common-interest privileges, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents already in Plaintiffs' possession, custody, or control or that have already been produced to Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 32:

Documents, communications, and things concerning any pre-clinical trials involving Zydus's ANDA Product.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents that are neither relevant to any party's claims or defenses nor proportional to the needs of this case, at least with respect to "[d]ocuments, communications, and things concerning any pre-clinical trials involving Zydus's ANDA Product." Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least

with respect to “[d]ocuments, communications, and things concerning.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, the joint-defense or common-interest privileges, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents already in Plaintiffs’ possession, custody, or control or that have already been produced to Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 33:

Documents, communications, and things concerning any clinical trials involving Zydus’s ANDA Product.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of this case, at least with respect to “[d]ocuments, communications, and things concerning any clinical trials involving Zydus’s ANDA Product.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications, and things concerning.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, the joint-defense or common-interest privileges, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents already in Plaintiffs’ possession, custody, or control or that have already been produced to Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 34:

Documents, communications, and things identifying and concerning each person, including, but not limited to, employees, agents, representatives, consultants, physicians, and collaborators, who participated in any research, development, design, using, testing, or marketing of Zydus's ANDA Product.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents that are neither relevant to any party's claims or defenses nor proportional to the needs of this case, at least with respect to "[d]ocuments, communications, and things identifying and concerning each person" and "including, but not limited to, employees, agents, representatives, consultants, physicians, and collaborators who participated in any research, development, design, using, testing, or marketing of Zydus's ANDA Product." Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to "[d]ocuments, communications, and things identifying and concerning each person, including, but not limited to, employees, agents, representatives, consultants, physicians, and collaborators" and "who participated in any research, development, design, using, testing, or marketing." Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, the joint-defense or common-interest privileges, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents already in Plaintiffs' possession, custody, or control or that have already been produced to Plaintiffs.

Subject to and without waiving any of its general and specific objections, and to the extent Zydus understands this Request, Zydus will produce non-privileged documents within Zydus's possession, custody, or control, if any, that are reasonably related to the research and development

of Zydus's Proposed ANDA Product. Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 35:

Documents, communications, and things identifying any declarations, affidavits, reports, or memoranda prepared by or for any expert or consultant with respect to Zydus's ANDA Product, including, but not limited to, any such declarations, affidavits, reports, and memoranda prepared in relation to any litigation or administrative proceeding involving Zydus's ANDA Product in the United States or any foreign country.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments communications, and things identifying any declarations, affidavits, reports, or memoranda prepared by or for any expert or consultant,” “any such declarations, affidavits, reports, and memoranda prepared in relation to any litigation or administrative proceeding involving Zydus's ANDA Product,” and “in the United States or any foreign country.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “any declarations, affidavits, reports, or memoranda,” and “in relation to any litigation or administrative proceeding.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents and things subject to confidentiality agreements, protective orders, or any other obligation to which Zydus is required to protect or maintain the confidentiality of any third party's information or documents. Zydus further objects to this Request to the extent it seeks information regarding expert discovery in advance of the deadlines set by this Court. Zydus further objects to this Request to the extent it seeks documents already in Plaintiffs' possession, custody, or control or

that have already been produced to Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus will produce expert reports and declarations consistent with the Court's Scheduling Order (D.I. 29). Zydus does not currently intend to produce any other documents in response to this Request.

REQUEST FOR PRODUCTION NO. 36:

Documents, communications, and things concerning any failure, shortcoming, deficiency, or limitation of Zydus's ANDA Product.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of this case, at least with respect to "[d]ocuments, communications, and things concerning any failure, shortcoming, deficiency, or limitation of Zydus's ANDA Product." Zydus further objects to this Request as vague, ambiguous, and failing to describe the documents identified with reasonable particularity, at least with respect to "[d]ocuments, communications, and things concerning any failure, shortcoming, deficiency, or limitation." Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 37:

Documents, communications, and things generated by persons engaged in any work, research, development, tests, experiments, evaluations, analyses, or studies, whether complete,

incomplete, or prematurely terminated on Xifaxan[®] by or for you, including, but not limited to, publications, research notebooks, research summaries, and reports.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things generated by persons engaged in any work, research, development, tests, experiments, evaluations, analyses, or studies whether complete, incomplete, or prematurely terminated” and “including, but not limited to, publications, research notebooks, research summaries, and reports.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications, and things generated by persons engaged in any work, research, development, tests, experiments, evaluations, analyses, or studies,” and “whether complete, incomplete, or prematurely terminated.” Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity.

Subject to and without waiving any of its general and specific objections, and to the extent Zydus understands this Request, Zydus will produce non-privileged documents within Zydus’s possession, custody, or control, if any, that are reasonably related to the polymorphs of rifaximin in Xifaxan[®]. Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 38:

Documents, communications, and things concerning all research, tests, experiments, evaluations, analyses, and studies performed by or for you on Xifaxan[®], including, but not limited

to, documents identifying the particular research, tests, experiments, evaluations, analyses, and studies performed, as well as when, where, and by whom they were performed and the results thereof.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things concerning all research, tests, experiments, evaluations, analyses, and studies performed by or for you on Xifaxan” and “documents identifying the particular research, tests, experiments, evaluations, analyses, and studies performed as well as when, where, and by whom they were performed and the results thereof.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications, and things concerning all research, tests, experiments, evaluations, analyses, and studies.” Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity.

Subject to and without waiving any of its general and specific objections, and to the extent Zydus understands this Request, Zydus will produce non-privileged documents within Zydus’s possession, custody, or control, if any, that are reasonably related to the polymorphs of rifaximin in Xifaxan®. Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 39:

Documents, communications, and things identifying any declarations, affidavits, reports, or memoranda prepared by or for any expert or consultant with respect to Xifaxan[®].

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things identifying any declarations, affidavits, reports, or memoranda,” and “prepared by or for any expert or consultant.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications, and things identifying any declarations, affidavits, reports, or memoranda.” Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks information regarding expert discovery in advance of the deadlines set by this Court.

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus will produce expert reports and declarations consistent with the Court’s Scheduling Order (D.I. 29). Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 40:

Documents, communications, and things identifying and concerning each person, including, but not limited to, employees, agents, representatives, consultants, and collaborators, who participated in any research, development, design, using, testing, or marketing of Xifaxan[®].

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things identifying and concerning each person” and “including, but not limited to, employees, agents, representatives, consultants, and collaborators, who participated in any research, development, design, using, testing, or marketing of Xifaxan[®].” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications, and things identifying and concerning each person” and “including, but not limited to, employees, agents, representatives, consultants, and collaborators, who participated in any research, development, design, using, testing, or marketing of Xifaxan[®].” Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity.

Subject to and without waiving any of its general and specific objections, and to the extent Zydus understands this Request, Zydus will produce non-privileged documents within Zydus’s possession, custody, or control, if any, that are reasonably related to the polymorphs of rifaximin in Xifaxan[®]. Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 41:

Documents, communications, and things concerning each bioavailability, bioequivalence, pharmacokinetics, stability, preservative efficacy, qualification, or validation study, whether

complete, incomplete, or prematurely terminated, that is being conducted or has been conducted by or for you concerning either Xifaxan[®] or Zydus's ANDA Product.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things concerning each bioavailability, bioequivalence, pharmacokinetics, stability, preservative efficacy, qualification, or validation study” and “whether complete, incomplete, or prematurely terminated, that is being conducted or has been conducted concerning either Xifaxan[®] or Zydus's ANDA Product.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications, and things concerning each bioavailability, bioequivalence, pharmacokinetics, stability, preservative efficacy, qualification, or validation study.” Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity.

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus has produced ANDA No. 218650 which contains bioequivalence studies for Zydus's Proposed ANDA Product and will produce amendments or supplements to ANDA No. 218650, if any, to the extent they have not already been produced. Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 42:

Documents, communications, and things concerning bioequivalence between Zydus's ANDA Product that you seek to market under ANDA No. 218650 and the rifaximin products under NDA No. 022554 and/or NDA No. 021361, including, but not limited to, documents identifying the batches or lots of the approved product of NDA No. 022554 and/or NDA No. 021361 that you analyzed in preparing your ANDA filing for ANDA No. 218650.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things concerning bioequivalence between Zydus’s ANDA Product that you seek to market under ANDA No. 218650 and the rifaximin products under NDA No. 022554 and/or NDA No. 021361.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications, and things concerning bioequivalence between Zydus’s ANDA Product that you seek to market under ANDA No. 218650 and the rifaximin products under NDA No. 022554 and/or NDA No. 021361.” Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity.

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus has produced ANDA No. 218650 which contains bioequivalence studies for Zydus’s Proposed ANDA Product and will produce amendments or supplements to ANDA No. 218650, if any, to the extent they have not already been produced. Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 43:

Documents and things concerning all communications between you and any governmental agency, including, but not limited to, FDA concerning ANDA No. 218650 and/or Zydus's ANDA Product.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments and things concerning all communications between you and any governmental agency” and “including, but not limited to, FDA concerning ANDA No. 218650 and/or Zydus's ANDA Product.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments and things concerning all communications between you and any governmental agency, including, but not limited to, FDA.” Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity.

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus has produced ANDA No. 218650 and correspondence with the FDA pertaining to ANDA No. 218650 and will produce amendments or supplements to ANDA No. 218650, if any, and additional correspondence with the FDA pertaining to ANDA No. 218650, if any, to the extent they have not already been produced. Zydus does not currently intend to produce any other documents in response to this Request.

REQUEST FOR PRODUCTION NO. 44:

Documents and things concerning all communications between you and any governmental agency concerning Xifaxan[®] and/or NDA No. 022554 and/or NDA No. 021361.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments and things concerning all communications between you and any governmental agency concerning Xifaxan[®] and/or NDA No. 022554 and/or NDA No. 021361.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments and things concerning all communications between you and any governmental agency.” Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 45:

Documents and things concerning all communications between you and any governmental agency concerning this litigation.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments and things concerning all communications between you and any governmental agency concerning this litigation.” Zydus further objects to

this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments and things concerning all communications between you and any governmental agency concerning this litigation.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 46:

Documents, communications, and things concerning any FOIA requests regarding any ANDAs for generic rifaximin tablets, including but not limited to the ANDAs submitted by Teva and Norwich.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments and things concerning any FOIA requests regarding any ANDAs for generic rifaximin tablets” and “including but not limited to the ANDAs submitted by Teva and Norwich.” Zydus further objects to this Request as vague, ambiguous, and failing to describe the documents identified with reasonable particularity, at least with respect to “[d]ocuments and things concerning any FOIA requests regarding any ANDAs for generic rifaximin tablets.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or

control of Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 47:

Documents and things concerning any communications between you and others regarding NDA No. 022554 and/or NDA No. 021361 and/or Xifaxan[®], including but not limited to, communications between you and Teva and/or you and Norwich.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments and things concerning any communications between you and others regarding NDA No. 022554 and/or NDA No. 021361 and/or Xifaxan[®].” Zydus further objects to this Request as vague, ambiguous, and failing to describe the documents identified with reasonable particularity, at least with respect to “[d]ocuments and things concerning any communications between you and others regarding NDA No. 022554 and/or NDA No. 021361 and/or Xifaxan[®]” and “communications between you and Teva and/or you and Norwich.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 48:

Documents, communications, and things concerning any Citizen Petition filed by or for you, or considered for filing by or for you, with FDA concerning Zydus’s ANDA Product, including all documents reviewed or considered by you in preparing any such Citizen Petition.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things concerning any Citizen Petition filed by or for you, or considered for filing by or for you, with FDA concerning Zydus’s ANDA product,” and “all documents reviewed or considered by you in preparing any such Citizen Petition.” Zydus further objects to this Request as vague, ambiguous, and failing to describe the documents identified with reasonable particularity, at least with respect to “[d]ocuments, communications, and things concerning any Citizen Petition filed by or for you, or considered for filing by or for you” and “all documents reviewed or considered by you.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 49:

Documents, communications, and things concerning any Citizen Petition filed by or for you, or considered for filing by or for you, with FDA concerning Xifaxan[®], including all documents reviewed or considered by you in preparing any such Citizen Petition.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things concerning any Citizen Petition filed by or for you, with FDA concerning Xifaxan[®],” and “all documents reviewed or considered by you in preparing any such Citizen Petition.” Zydus further objects to

this Request as vague, ambiguous, and failing to describe the documents identified with reasonable particularity, at least with respect to “[d]ocuments, communications, and things concerning any Citizen Petition filed by or for you, or considered for filing by or for you” and “all documents reviewed or considered by you.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 50:

Documents, communications, and things concerning your preparation and filing of any patent certification to FDA regarding the Xifaxan[®] Patents.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things concerning your preparation and filing of any patent certification to FDA regarding the Xifaxan[®] Patents.” Zydus further objects to this Request as vague, ambiguous, and failing to describe the documents identified with reasonable particularity, at least with respect to “[d]ocuments, communications, and things concerning your preparation and filing of any patent certification.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents and things that

have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 51:

Documents, communications, and things concerning the preparation of your Notice Letter.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things concerning your preparation of your Notice Letter.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications, and things concerning your preparation.” Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 52:

Documents, communications, and things that you relied upon in support of your assertion in your Notice Letter dated August 15, 2024 that pursuant to 21 C.F.R. § 314.95(c)(6), “no valid and enforceable claim of the [Xifaxan[®] Patents] will be infringed by the importation, manufacture, use, or sale of Zydus’s proposed ANDA product.”

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and to the extent it seeks documents and information that are neither relevant to the claims or defenses of any party nor proportional to the needs of this case, at least with respect to “[d]ocuments, communications, and things that you relied upon in support of your assertion in your Notice Letter dated August 15, 2024 that pursuant to 21 C.F.R. § 314.95(c)(6), ‘no valid and enforceable claim of the [Xifaxan[®] Patents] will be infringed by the importation, manufacture, use, or sale of Zydus’s proposed ANDA product.’” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications, and things you relied upon in support of your assertion.” Zydus further objects to this Request as premature to the extent it seeks documents and things regarding expert discovery in advance of the deadlines set by the Court’s Scheduling Order (D.I. 29). Zydus further objects to this Request to the extent it seeks documents or information already in Plaintiff’s possession, custody, or control, and/or that have already been produced to Plaintiff. Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 53:

Documents and things concerning any communications between or among your employees, management, agents, or attorneys concerning Zydus’s ANDA Product, including but not limited to, polymorphic forms of rifaximin, clinical trials, *in vivo* or *in vitro* bioequivalence studies, stability studies, and communications with FDA regarding Zydus’s ANDA Product.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and to the extent it seeks documents and information that are neither relevant to the claims or defenses of any party nor

proportional to the needs of this case, at least with respect to “[d]ocuments, and things concerning any communications between or among your employees, management, agents, or attorneys concerning Zydus’s ANDA Product” and “including but not limited to, polymorphic forms of rifaximin, clinical trials, in vivo or in vitro bioequivalence studies, stability studies, and communications with FDA regarding Zydus’s ANDA Product.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments and things concerning any communications.” Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity.

Subject to and without waiving any of its general and specific objections, and to the extent Zydus understands this Request, Zydus will produce non-privileged documents within Zydus’s possession, custody, or control, if any, that are reasonably related to the research and development of Zydus’s Proposed ANDA Product. Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 54:

Documents and things concerning any communications between or among your employees, management, agents, or attorneys concerning the Xifaxan[®] Patents.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments and things concerning any communications between or among your employees, management, agents, or attorneys.” Zydus

further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments and things concerning any communications between or among your employees, management, agents, or attorneys.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 55:

Documents and things concerning any communications between or among your employees, management, agents, or attorneys concerning this litigation.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments and things concerning any communications between or among your employees, management, agents, or attorneys.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments and things concerning any communications between or among your employees, management, agents, or attorneys” and “concerning this litigation.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or

control of Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 56:

Documents and things concerning any communications between or among your employees, management, agents, or attorneys concerning Xifaxan[®]'s market exclusivity or loss thereof.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments and things concerning any communications between or among your employees, management, agents, or attorneys concerning Xifaxan[®]'s market exclusivity or loss thereof.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments and things concerning any communications between or among your employees, management, agents, or attorneys.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 57:

Documents, communications, and things concerning any draft, proposed, or actual press releases, publicity releases, trade releases, new product releases, or other trade notices prepared by or for you concerning your ANDA filing for ANDA No. 218650 and/or Zydus's ANDA Product.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things concerning any draft, proposed, or actual press releases, publicity releases, trade releases, new product releases, or other trade notices prepared by or for you.” Zydus objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications, and things concerning any draft, proposed, or actual press releases, publicity releases, trade releases, new product releases, or other trade notices prepared by or for you.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 58:

Documents and things concerning all communications between you and investors concerning this litigation.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments and things concerning any communications between you and investors concerning this litigation.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity,

at least with respect to “[d]ocuments and things concerning any communications between you and investors concerning this litigation.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 59:

Documents and things concerning any communications or contacts between you and any other person (excluding Plaintiffs) concerning the Xifaxan[®] Patents.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments and things concerning any communications or contacts between you and any other person (excluding Plaintiffs) concerning the Xifaxan[®] Patents.” Zydus objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments and things concerning any communications or contacts.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 60:

Documents, communications, and things concerning the Xifaxan[®] Patents, including, but not limited to, all documents, communications, and things concerning any study, analysis, report, or legal opinion, whether written or oral, concerning the Xifaxan[®] Patents.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things concerning the Xifaxan[®] Patents” and “including, but not limited to, all documents, communications, and things concerning any study, analysis, report, or legal opinion, whether written or oral, concerning the Xifaxan[®] Patents.” Zydus objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications, and things concerning the Xifaxan[®] Patents,” and “all documents, communications, and things concerning any study, analysis, report, or legal opinion.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus further objects to this Request as premature to the extent it seeks documents and things regarding expert discovery in advance of the deadlines set by the Court’s Scheduling Order (D.I. 29).

Subject to and without waiving any of its general and specific objections, and to the extent Zydus understands this Request, Zydus will provide its noninfringement contentions, invalidity contentions, expert reports, and declarations, and associated documents consistent with the Court’s Scheduling Order (D.I. 29). Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 61:

Documents, communications, and things concerning any alleged Prior Art to the Xifaxan[®] Patents.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of this case, at least with respect to “[d]ocuments, communications, and things concerning any alleged Prior Art to the Xifaxan[®] Patents.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications, and things concerning any alleged Prior.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent that it seeks documents or information that is already in Plaintiffs’ possession, custody, or control, and/or has already been produced to Plaintiffs. Zydus further objects to this Request to the extent it seeks information regarding expert discovery in advance of the deadlines set by the Court’s Scheduling Order (D.I. 29).

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus will provide its invalidity contentions, expert reports, and associated documents consistent with the Court’s Scheduling Order (D.I. 29). Zydus does not intend to produce any other documents in response to this Request.

REQUEST FOR PRODUCTION NO. 62:

Documents, communications, and things sufficient to show the organizational relationship of you and all corporations or other entities related to you.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things sufficient to show the organizational relationship of you and all corporations or other entities related to you.” Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to “[d]ocuments, communications, and things sufficient to show the organizational relationship.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent that it seeks documents or information that is already in Plaintiffs’ possession, custody, or control, and/or has already been produced to Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 63:

All charts, outlines, pyramids, diagrams, or other documents sufficient to describe and identify your organizational structure and personnel responsible for managing any research, development, design, testing, evaluation, manufacture, production, marketing, distribution, or sale of Zydus’s ANDA Product.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[a]ll charts, outlines, pyramids, diagrams, or other documents sufficient to identify your organization structure” and “personnel responsible for managing any research, development, design, testing, evaluation, manufacture, production, marketing, distribution, or sale of Zydus’s ANDA Product.” Zydus further objects to this Request

as vague, ambiguous, and failing to describe the documents identified with reasonable particularity, at least with respect to “[a]ll charts, outlines, pyramids, diagrams, or other documents sufficient to identify” and “managing any research, development, design, testing, evaluation, manufacture, production, marketing, distribution, or sale.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent that it seeks documents or information that is already in Plaintiffs’ possession, custody, or control, and/or has already been produced to Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 64:

Documents, communications, and things concerning any document retention policy or program that you have in place.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things concerning any document retention policy or program that you have in place.” Zydus further objects to this Request as vague, ambiguous, and failing to describe the documents identified with reasonable particularity, at least with respect to “[d]ocuments and things concerning any document retention policy or program that you have in place.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent that it seeks documents or information that is already in Plaintiffs’ possession,

custody, or control, and/or has already been produced to Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 65:

Documents, communications, and things relied upon or referred to by you in responding to Plaintiffs' requests for admission to you in this litigation.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to "[d]ocuments, communications, and things relied upon or referred to by you in responding to Plaintiffs' requests for admission to you in this litigation." Zydus further objects to this Request as vague, ambiguous, and failing to describe the documents identified with reasonable particularity, at least with respect to "[d]ocuments, communications, and things relied upon or referred to by you" and "in responding to Plaintiffs' requests for admission to you in this litigation." Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent that it seeks documents or information that is already in Plaintiffs' possession, custody, or control, and/or has already been produced to Plaintiffs.

Subject to and without waiving any of its general and specific objections, and to the extent Zydus understands this Request, Zydus states that Plaintiffs have not served any requests for admission. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 66:

Documents, communications, and things relied upon or referred to by you in responding to Plaintiffs' interrogatories to you in this litigation.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things relied upon or referred to by you in responding to Plaintiffs’ interrogatories to you in this litigation.” Zydus further objects to this Request as vague, ambiguous, and failing to describe the documents identified with reasonable particularity, at least with respect to “[d]ocuments, communications, and things relied upon or referred to by you.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent that it seeks documents or information that is already in Plaintiffs’ possession, custody, or control, and/or has already been produced to Plaintiffs.

Subject to and without waiving any of its general and specific objections, and to the extent Zydus understands this Request, Zydus will produce documents identified in Zydus’s Objections and Responses to Plaintiffs’ First Set of Interrogatories (No. 1-11), if any. Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 67:

Documents, communications, and things relied upon by you in preparing your Answer, Defenses, and Counterclaims in this litigation.

RESPONSE:

Zydus objects to this Request as overly broad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of the case, at least with respect to “[d]ocuments, communications, and things relied upon by you in preparing your Answer, Defenses, and Counterclaims in this litigation.” Zydus further

objects to this Request as vague, ambiguous, and failing to describe the documents identified with reasonable particularity, at least with respect to “[d]ocuments, communications, and things relied upon by you.” Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent that it seeks documents or information that is already in Plaintiffs’ possession, custody, or control, and/or has already been produced to Plaintiffs. Zydus does not currently intend to produce any documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 68:

Documents, communications, and things you intend to rely upon or use as an exhibit, demonstrative, or evidence at any hearing or trial.

RESPONSE:

Zydus objects to this Request as vague, ambiguous, and failing to describe the documents identified with reasonable particularity, at least with respect to “[d]ocuments, communications, and things you intend to rely upon or use as an exhibit, demonstrative, or evidence at any hearing or trial.” Zydus further objects to this Request as vague, ambiguous, and failing to describe the documents identified with reasonable particularity, at least with respect to “[d]ocuments, communications, and things you intend to rely upon or use as an exhibit, demonstrative, or evidence at any hearing or trial.” Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks information regarding expert discovery in advance of the deadlines set by the Court’s Scheduling

Order (D.I. 29). Zydus further objects to this Request to the extent that it requires Zydus to provide trial exhibits, demonstratives, and evidence in advance of the deadlines set by the Court's Scheduling Order (D.I. 29).

Subject to and without waiving any of its general and specific objections, and to the extent Zydus understands this Request, Zydus will provide trial exhibits, demonstratives, and evidence consistent with the Court's Scheduling Order (D.I. 29). Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 69:

Documents, communications, and things that an expert or consultant retained by you relies upon or uses in support of an expert report and/or opinion offered in this litigation.

RESPONSE:

Zydus objects to this Request as vague, ambiguous, and failing to describe the documents identified with reasonable particularity, at least with respect to "[d]ocuments, communications, and things that an expert or consultant retained by you relies upon or uses in support of an expert report and/or opinion offered in this litigation." Zydus further objects to this Request as vague, ambiguous, and failing to describe the documents identified with reasonable particularity, at least with respect to "[d]ocuments, communications, and things that an expert or consultant retained by you relies upon or uses." Zydus further objects to this Request to the extent it seeks documents and things that have already been produced to or are in the possession, custody, or control of Plaintiffs. Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent it seeks information regarding expert discovery in advance of the deadlines set by the Court's Scheduling Order (D.I. 29).

Subject to and without waiving any of its general or specific objections, and to the extent Zydus understands this Request, Zydus will produce expert reports and declarations consistent with the Court's Scheduling Order (D.I. 29) and provide any disclosures required by Fed. R. Civ. P. 26(a)(2). Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 70:

Documents, communications, and things that support, or may support, Plaintiffs' allegations of infringement of any claims of the Xifaxan[®] Patents.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of this case, at least with respect to "[d]ocuments, communications, and things that support, or may support, Plaintiffs' allegations of infringement of any claims of the Xifaxan Patents." Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to "[d]ocuments, communications, and things that support, or may support, Plaintiffs' allegations of infringement." Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent that it seeks documents or information that is already in Plaintiffs' possession, custody, or control, and/or has already been produced to Plaintiffs. Zydus further objects to this Request to the extent it seeks information regarding expert discovery in advance of the deadlines set by the Court's Scheduling Order (D.I. 29).

Subject to and without waiving any of its general and specific objections, and to the extent Zydus understands this Request, Zydus will provide its noninfringement contentions, invalidity contentions, expert reports, and declarations, and associated documents consistent with the Court's Scheduling Order (D.I. 29). Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 71:

Documents, communications, and things that support, or may support, Plaintiffs' allegations of the validity of any claims of the Xifaxan[®] Patents.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of this case, at least with respect to "[d]ocuments, communications, and things that support, or may support, Plaintiffs' allegations of the validity of any claims of the Xifaxan[®] Patents." Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to "[d]ocuments, communications, and things that support, or may support, Plaintiffs' allegations of the validity." Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent that it seeks documents or information that is already in Plaintiffs' possession, custody, or control, and/or has already been produced to Plaintiffs. Zydus further objects to this Request to the extent it seeks information regarding expert discovery in advance of the deadlines set by the Court's Scheduling Order (D.I. 29).

Subject to and without waiving any of its general and specific objections, and to the extent Zydus understands this Request, Zydus will provide its noninfringement contentions, invalidity contentions, expert reports, and declarations, and associated documents consistent with the Court's Scheduling Order (D.I. 29). Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 72:

Documents, communications, and things that support, or may support, Zydus's assertion in its counterclaims that the claims of the Xifaxan[®] Patents are "invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112."

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of this case, at least with respect to "[d]ocuments, communications, and things that support, or may support, Zydus's assertion in its counterclaims that the claims of the Xifaxan[®] are 'invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.'" Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to "[d]ocuments, communications, and things that support, or may support, Zydus's assertion in its counterclaims." Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent that it seeks documents or information that is already in Plaintiffs' possession, custody, or control, and/or has already been produced to Plaintiffs. Zydus further objects to this

Request to the extent it seeks information regarding expert discovery in advance of the deadlines set by the Court's Scheduling Order (D.I. 29).

Subject to and without waiving any of its general and specific objections, and to the extent Zydus understands this Request, Zydus will provide its noninfringement contentions, invalidity contentions, expert reports, and declarations, and associated documents consistent with the Court's Scheduling Order (D.I. 29). Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 73:

Documents, communications, and things that support, or may support, Zydus's assertion in its counterclaims that the '571 patent, '912 patent, '196 patent, '949 patent, '904 patent, '968 patent, and '763 patents "are invalid and/or not infringed by Zydus and the product described in Zydus'[s]" ANDA No. 218650.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of this case, at least with respect to "[d]ocuments, communications, and things that support, or may support, Zydus's assertion in its counterclaims that the '571 patent, '912 patent, '196 patent, '949 patent, '904 patent, '968 patent, and '763 patents 'are invalid and/or not infringed by Zydus and the product described in Zydus'[s]' ANDA No. 218650." Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to "[d]ocuments, communications, and things that support, or may support, Zydus's assertion in its counterclaims." Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent that it seeks documents or information that is already in

Plaintiffs' possession, custody, or control, and/or has already been produced to Plaintiffs. Zydus further objects to this Request to the extent it seeks information regarding expert discovery in advance of the deadlines set by the Court's Scheduling Order (D.I. 29).

Subject to and without waiving any of its general and specific objections, and to the extent Zydus understands this Request, Zydus will provide its noninfringement contentions, invalidity contentions, expert reports, and declarations, and associated documents consistent with the Court's Scheduling Order (D.I. 29). Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 74:

Documents, communications, and things that support, or may support, Zydus's counterclaims for declaratory judgment of non-infringement and invalidity of the '571 patent, '912 patent, '196 patent, '949 patent, '904 patent, '968 patent, and '763 patent.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of this case, at least with respect to "[d]ocuments, communications, and things that support, or may support, Zydus's counterclaims for declaratory judgment of non-infringement and invalidity of the '571 patent, '912 patent, '196 patent, '949 patent, '904 patent, '968 patent, and '763 patent." Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to "[d]ocuments, communications, and things that support, or may support, Zydus's counterclaims for declaratory judgment." Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent that it seeks documents or information that is already in Plaintiffs' possession, custody, or control, and/or

has already been produced to Plaintiffs. Zydus further objects to this Request to the extent it seeks information regarding expert discovery in advance of the deadlines set by the Court's Scheduling Order (D.I. 29).

Subject to and without waiving any of its general and specific objections, and to the extent Zydus understands this Request, Zydus will provide its noninfringement contentions, invalidity contentions, expert reports, and declarations, and associated documents consistent with the Court's Scheduling Order (D.I. 29). Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 75:

Documents, communications, and things that support, or may support, Zydus's counterclaims requiring de-listing of the '196 patent, '949 patent, '968 patent, '904 patent and '763 patent from the Orange Book.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of this case, at least with respect to "[d]ocuments, communications, and things that support, or may support, Zydus's counterclaims requiring de-listing of the '196 patent, '949 patent, '968 patent, '904 patent and '763 patent from the Orange Book." Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to "[d]ocuments, communications, and things that support, or may support, Zydus's counterclaims." Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent that it seeks documents or information that is already in Plaintiffs' possession, custody, or control, and/or has already been produced to Plaintiffs. Zydus further objects to this Request to

the extent it seeks information regarding expert discovery in advance of the deadlines set by the Court's Scheduling Order (D.I. 29).

Subject to and without waiving any of its general and specific objections, and to the extent Zydus understands this Request, Zydus will provide its expert reports, and declarations, and associated documents consistent with the Court's Scheduling Order (D.I. 29). Zydus does not currently intend to produce any other documents or things in response to this Request.

REQUEST FOR PRODUCTION NO. 76:

Documents, communications, and things that support, or may support, any assertion by Zydus that the Federal Circuit's decision in *Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056 (Fed. Cir. 2024) is relevant to this litigation, including, but not limited to, the validity of the Xifaxan® Patents.

RESPONSE:

Zydus objects to this Request as overbroad, unduly burdensome, and seeking documents and things that are neither relevant to the claims or defenses of any party nor proportional to the needs of this case, at least with respect to "[d]ocuments, communications, and things that support, or may support, any assertion by Zydus that the Federal Circuit's decision in *Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056 (Fed. Cir. 2024) is relevant to this litigation, including, but not limited to, the validity of the Xifaxan® Patents." Zydus further objects to this Request as vague, ambiguous, and failing to identify the documents requested with reasonable particularity, at least with respect to "[d]ocuments, communications, and things that support, or may support, any assertion by Zydus." Zydus further objects to this Request to the extent that it seeks documents or information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. Zydus further objects to this Request to the extent that it seeks documents or information that is already in Plaintiffs' possession, custody, or control, and/or has already been produced to Plaintiffs. Zydus further objects to this Request to the extent it seeks

information regarding expert discovery in advance of the deadlines set by the Court's Scheduling Order (D.I. 29).

Subject to and without waiving any of its general and specific objections, and to the extent Zydus understands this Request, Zydus will provide its contentions, expert reports, and declarations, and associated documents consistent with the Court's Scheduling Order (D.I. 29). Zydus does not currently intend to produce any other documents or things in response to this Request.

Dated: March 19, 2025

By: s/ Theodora McCormick

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CERTIFICATE OF SERVICE

I certify that, on March 19, 2025, I caused a true copy of Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited's Objections and Responses to Plaintiffs' First Set of Requests to Defendants for the Production of Documents and Things (Nos. 1-76) to be served upon plaintiffs' counsel of record via email.

Dated: March 19, 2025

s/ Theodora McCormick

Theodora McCormick